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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,343	12/22/2005	Udo Krupka	05552.1464	5936

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EXAMINER	
HURT, SHARON L	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,343	KRUPKA, UDO	
	Examiner	Art Unit	
	Sharon Hurt	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-35 and 41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24,26,28,29,31,33-35 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/20/2005, 6/23/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 24-35 and 41, and species, SEQ ID NO: 12 in the reply filed on September 18, 2006 is acknowledged. The traversal is on the ground(s) that "the instant claims are so linked as to form a single general inventive concept". Applicant argues that all the claims "contain the same or corresponding special technical feature". This is not found persuasive because the groups are drawn to distinct inventions. Group I is drawn to an oligonucleotide or polypeptide comprising an amino acid sequence. Group II is drawn to an antibody, Group III is drawn to an antiidiotypic antibody, Group IV is drawn to a kit and Group V is drawn to a method of identifying antibodies. Groups II-V can be used with a materially different product and are distinctly different from Group I. Therefore the groups do not form a single inventive concept and share the same special technical feature.

The requirement is still deemed proper and is therefore made FINAL.

Claims 36-40 and 42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 18, 2006.

Claim Objections

Claims 29 and 41 are objected to because of the following informalities: The claims contain reference to a non-elected invention. Claim 33 is objected to because the claim contains a typographical error in line 3, "H8V". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites "an amino acid sequence with at least 78% identity to SEQ ID NO:14". The phrase "at least 78% identity" fails to define the meets and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24, 26, 28-29, 31, 33-35 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Stuyver et al. (WO 01/40279 A2, 7 June 2001).

The claimed invention is drawn to an oligopeptide or polypeptide comprising an amino acid sequence with at least 78% identity to SEQ ID NO:14, wherein 0 to 10 amino acids are substituted, deleted or inserted as compared with SEQ ID NO:14, wherein an oligopeptide or polypeptide comprising at least 5 consecutive amino acids from SEQ ID NO:12 and comprising

at least one of the amino acid positions 54, 61, 72, 73, 74, 75, 76, 78, 85, 87 and 94 of SEQ ID NO:12, wherein the amino acid sequence is SEQ ID NO:12, wherein an oligopeptide or polypeptide comprising at least 5 consecutive amino acids, and comprising at least one of the amino acid positions 96, 103, 114, 115, 116, 117, 118, 120, 127, 129, and 136 of SEQ ID NO:12, wherein position 96 is alanine, position 103 is isoleucine, position 114 is alanine, position 115 is isoleucine, position 116 is asparagine, position 117 is asparagine, position 118 is arginine, position 120 is glutamine, position 127 is threonine, position 129 is histadine and position 136 is tyrosine. The claimed invention is also drawn to a composition comprising at least one immunogenic molecule comprising one or more oligopeptides or polypeptides as claimed above and optionally further comprising one or more HBV immunogens. The claimed invention is also drawn to a method of preparing the oligopeptide or polypeptide as claimed above, which comprises culturing a cell and expressing the oligopeptide or polypeptide, wherein the oligopeptide or polypeptide is isolated from the cells and separated from the other oligopeptides or polypeptides, and a method for detecting a hepatitis B antigen, comprising (a) incubating a sample with the antibody under conditions which allow the formation of antigen-antibody complexes; and (b) detecting antigen-antibody complexes.

Stuyver et al. (hereinafter Stuyver) teaches about a HBsAG amino acid sequence with 78.8% identity to SEQ ID NO:14 (see Example 3 and Figure 6). Stuyver teaches about a HBsAG amino acid sequence with 93.4% identity to SEQ ID NO:12 (see Example 3 and Figure 6). The sequence in the reference meets the limitations of 0 to 10 amino acids altered as compared to SEQ ID NO:14 (see Example 3 and Figure 6). The reference also meets the limitation of at least 5 consecutive amino acids from SEQ ID NO:12 (see Example 3 and Figure

6). The reference teaches SEQ ID NO:12 and position 115 is isoleucine (see Example 3 and Figure 6). Stuyver teaches about a method for the production of the polypeptide (page 4, lines 7-8). Stuyver teaches about a host cell expressing the polypeptide (page 4, lines 11-12). Stuyver teaches about a method for the detection of antibodies that recognize HBV (page 4, lines 13-14).

Claims 25, 27, 30 and 32 are free of the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

22 December 2006

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